EXHIBIT J

- **Marah C. Hehemann, et al., *Penile Girth Enlargement Strategies: What's the Evidence?***

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SEXUAL MEDICINE REVIEWS REVIEW

Penile Girth Enlargement Strategies: What's the Evidence?

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ABSTRACT

Introduction: Most men seeking penile girth augmentation have physiologically normal penises but may suffer from severe preoccupation with penis size known as *penile dysmorphophobic disorder*.

Aim: To describe the medical, procedural, and reconstructive techniques available for penile girth enhancement and to review the success and complications of each modality.

Methods: A comprehensive review of peer-reviewed publications on the topic was performed through a PubMed search. Key search terms included penis, enhancement, enlargement, phalloplasty, reconstruction, girth, and augmentation.

Main Outcome Measure: We wanted to summarize the motivations behind penile girth enhancement and review the outcomes for girth augmentation treatments.

Results: Various medical, traction, injection, prosthetic, and reconstructive modalities have been studied for penile girth enhancement, with increases in girth ranging from 0-4.9 cm. Complications were reported in a minority of patients, but they may be devastating and include penile fibrosis, sexual dysfunction, device infection, and death.

Conclusion: A variety of penile girth augmentation techniques have been studied. Clinical guidelines are lacking, and complications of penile girth enhancement are likely underreported. Until more rigorous investigation with accurate reporting of complications is achieved, penile girth augmentation procedures should be considered experimental. **Hehemann MC, Towe M, Huynh LM, et al. Penile Girth Enlargement Strategies: What's the Evidence? Sex Med 2019;7:535–547.**

Key Words: Penile Augmentation; Penile Enhancement; Penile Girth; Phalloplasty; Penile Dysmorphophobic Disorder

INTRODUCTION

Throughout history, the penis has been regarded as the dominant symbol of masculinity, engendering significant anxiety about penile length and girth in many men.[1,2] Although the average erect penile length and girth are 13.1 and 11.65 cm, respectively, men who perceive their penis to be smaller than average account for as much as 91% of the general population.[3,4] Because this preconception is further proliferated by mainstream media, men are increasingly seeking medical solutions for "inadequate" size.[5] Although numerous indications and strategies exist for penile lengthening, there is neither clinical recommendation nor current literature that adequately describes motivations or strategies solely for penile girth enlargement.[5,6] In distinction to girth restoration (eg, in those undergoing surgical treatment for Peyronie's disease [PD]), girth enhancement is typically performed only for cosmetic and psychological reasons—similar to that seen with breast augmentation.[7] In this review, we highlight potential motivations behind penile girth enlargement, as well as the various medical, traction, injection, prosthetic, and reconstructive modalities commonly used in urologic and plastic specialties (Table 1).

PENILE DYSMORPHOPHOBIA

Most men who seek penile augmentation have a normal-sized penis by clinical standards.[21,22] These men may suffer from penile dysmorphophobic disorder (PDD), a subtype of body dysmorphic disorder (BDD) that is defined in the *Diagnostic and Statistical Manual for Mental Disorders*, Fifth Edition, as a preoccupation with a minor or non-existent flaw in body image that

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Table 1. Summary of clinically relevant studies on different penile girth augmentation modalities

Study	Treatment modality	Design	n	Mean follow-up period, mo	Penile girth increase, cm	Complications	Satisfaction
Aghamir et al[8]	Vacuum erectile device	Prospective	30	8	Not reported	No serious complications	30% satisfied with treatment
Gontero et al[9]	Traction therapy	Prospective	21	6	0.03, clinically insignificant	No serious complications	Improvement in IIEF, poor satisfaction with penile girth
Nowroozi et al[10]	Traction therapy	Prospective	44	3	0.02, clinically insignificant	No serious complications	27% moderate improvement, 55% mild improvement
Panfilov[11]	Autologous fat injection	Retrospective	88	12	2.65	Preputial injection requiring removal (n = 1)	88% highly satisfied, 9% fairly satisfied, 3% unsatisfied
Kang et al[12]	Autologous fat injection	Retrospective	52	6	2.3	No serious complications	75% satisfaction
Yacobi et al[13]	Liquid injectable silicone (microdroplet)	Retrospective	324 (data on 30)	20	2.6	No serious complications	High satisfaction, 21 patients with improved erections and resolution of premature ejaculation
Kwak et al[14]	Hyaluronic acid injection	Prospective	41	18	3.8	No serious complications	Diminished satisfaction with long-term follow-up, decreased tactile sensation, decreased erectile rigidity
Casavantes et al[15]	Polymethyl-methacrylate injection	Retrospective	729	Not reported	2.4	No serious complications; 52% palpable shaft abnormalities, 0.4% required PMMA nodule removal	In n = 203, 83% satisfaction, 17% not satisfied/dissatisfied
Spyropoulos et al[16]	Dermal fat graft	Retrospective	4	14	2.3	Graft sclerosis, preputial edema, paraphimosis, pain with erection	Favorable outcomes on APPSSI score
Alei et al[17]	Porcine dermal acellular matrix graft	Retrospective	69	12	3.2 flaccid, 2.4 erect	13% graft fibrosis resulting in penile retraction	98% satisfaction on APPSSI

(continued)

causes marked impairment in various areas of functioning.[23] In men with PDD, the perceived flaw is the size or appearance of the penis. Similarly, some men may have small penis anxiety (SPA), which involves excessive fear or worry of one's external genitalia being observed and negatively evaluated by others due to size. Both PDD and SPA exclude men with a true micropenis, which has been described as a flaccid penis length <4 cm and an erect penis length <7.5 cm.[24]

Men with PDD can suffer from intense feelings of shame and embarrassment with regard to their penis size, thus leading to a decreased quality of life. Recent literature suggests that men with PDD have greater shame and interference with relationships than men with SPA and control subjects.[25] They also exhibit more avoidance and safety-seeking behaviors in situations where their genitalia may be displayed (eg, in a locker room or with a sexual partner). Similarly, distress over subjective penile size can negatively affect sexual functioning. A recent study showed that patient-reported small penile size was associated with erectile dysfunction, irrespective of actual measured penile size.[26] Additionally, men who are abnormally concerned about the size of their penis are at risk of developing feelings of low self-esteem and mood in general. Veale et al[27] attempted to measure the shame on an 18-item scale and found it to be positively correlated with depressive and anxiety symptoms.

Goals of the girth enhancement strategies reviewed here are increasing penile circumference in both the flaccid and erect states while maintaining a natural, uniform-appearing shaft and integrity of the patient's sensory and erectogenic capacity. However, because PDD is first and foremost a psychological diagnosis, thorough psychosexual, psychological, psychiatric, as well as urologic evaluations should be completed before embarking on girth augmentation. Additionally, investigators studying penile girth enhancement techniques should place high value on psychosocial outcomes measured with validated instruments.

MEDICAL THERAPY

The principal goals of oral therapies for treatment of PDD are 2-fold: to produce an objective increase in penile girth and to treat the psychological distress associated with PDD. Purporting to address the first goal, over-the-counter, poorly regulated penile enhancement supplements are vast in number and pervasive throughout web-based advertising. These "natural male enhancement" products represent part of the nutraceuticals industry, a market that is projected to reach more than $578 billion by 2025.[28] Although the popularity of these products is evident by the magnitude of consumer spending dedicated to them, Food and Drug Administration (FDA) approval is lacking, and there are no scientific data to support their use for penile girth augmentation. Additionally, such dietary supplements are known to contain undeclared and potentially dangerous substances.[29] Physicians treating men with PDD should discuss with

Table 1. Continued

Study	Treatment modality	Design	n	Mean follow-up period, mo	Penile girth increase, cm	Complications	Satisfaction
Tealab et al[18]	Acellular collagen matrix graft	Retrospective	18	12	2.3	22% edema and ulceration requiring graft removal, 22% diminished sensation	11% with high postoperative satisfaction
Elist et al[19]	Subcutaneous silicone implant	Retrospective	400	48	4.9	3% required device removal because of infection, perforation, detachment, breakage, hematoma	81% high or very high satisfaction, 72% improved APPSSI score
Austoni et al[20]	Corporal venous graft	Retrospective	39	9	2.9 (erect), flaccid girth unchanged	No major complications	Not evaluated

APPSSI = Augmentation Phalloplasty Patient Selection and Satisfaction Inventory; IIEF = International Index of Erectile Function.

their patients the use of non-regulated supplements and caution against their consumption.

The oral phosphodiesterase type 5 (PDE5) inhibitor class is considered first-line treatment for men with erectile dysfunction.[30] By diminishing the degradation of intracellular cyclic guanosine monophosphate in cavernosal smooth muscle cells, PDE5 inhibitors create a downstream relaxation of arterial and trabecular smooth muscle, thereby increasing arterial inflow, reducing penile venous outflow, and producing penile rigidity.[31] Although this mechanism works well to generate physiological erection, PDE5 inhibitors have also been found to have significant implications in regeneration of penile smooth muscle and in tissue remodeling. In the PD animal model and human PD subjects, administration of daily PDE5 inhibitor was found to produce restorative effects on corporal smooth muscle content and a reduction in collagen content in both PD plaques and corporal bodies.[32,33] Furthermore, daily PDE5 inhibitor use can mitigate corporal remodeling and smooth muscle apoptosis in the rat radical prostatectomy (RP) model and was confirmed by Schwartz et al[34] in human subjects with good sexual function prior to RP.[35,36] The ability for PDE5 inhibitors to produce an increase in corporal smooth muscle and to prevent its degradation is the concept on which post-RP penile rehabilitation was developed.[37]

Although there is a large body of literature on PDE5 inhibitor use in penile rehabilitation, there is an absence of data looking at the use of PDE5 inhibitors in men with PDD. Whether these pharmaceuticals have efficacy in producing an increase in muscle content and penile girth in the physiologically normal penis is unknown and requires further scientific study.

Investigations should also be made into the utility of PDE5 inhibitors in combination with psychotherapy to promote confidence and to mitigate the psychological distress of PDD. Combining sildenafil with group therapy has been effective for men with psychogenic erectile dysfunction (ED), and this non-invasive, low-cost strategy is deserving of further study in PDD.[38,39]

Fluoxetine, a well-tolerated selective serotonin reuptake inhibitor, has also been demonstrated to improve the symptoms of patients with BDD in a randomized, placebo-controlled trial.[40] Patients with both delusional and non-delusional symptoms were found to have improved parameters on validated outcome measures after 12 weeks of therapy. Because PDD is a subtype of BDD, further use and investigation of this drug in men with PDD is warranted.

VACUUM AND TRACTION THERAPY

Vacuum erectile devices can temporarily increase the size of the penis by drawing blood into the corpora cavernosa; however, the ability to create a long-term, lasting change in penile length and girth is debated. Aghamir et al[8] performed a prospective, non-blinded, cohort study of regular vacuum therapy to determine sustained penile size gain. 31 men performed approximately 20 minutes of vacuum therapy 3 times weekly for 6 months, and the majority (87%) presented for follow-up at a mean of 8 months. The authors reported no significant length gained in the cohort, with only 11% of the men achieving ≥1 cm of length gained. This study does not specify girth parameters, but with proven lack of tissue expansion longitudinally, one can extrapolate that girth expansion would also be lacking. Additionally, satisfaction with treatment was poor, with only 30% of patients reporting reasonable satisfaction, making this treatment option untenable.

Penile traction devices use the principle of continuous mechanical force transduction across a tissue plane to produce tissue remodeling, much like dental braces are used to induce bone remodeling and correct tooth alignment. In a prospective, pilot study, Gontero et al[9] sought to answer whether penile traction can induce long-term penile augmentation in men with PDD. 16 of 21 enrolled patients completed the study protocol, which included traction device application for 4–6 hours per day for 6 months. The authors reported significant length gained (mean length gained 2.3 cm flaccid, 1.7 cm stretched), with the greatest change in length occurring during the first month of therapy. Despite these encouraging outcomes for men with PDD, increases in penile girth were clinically insignificant (0.03 cm), and patients reported no appreciable change.[9] Nowroozi et al[10] confirmed these results in the largest investigation to date regarding traction therapy in men with PDD and normal penile size (≥7.5 cm). After psychiatric evaluation and counseling, participants were instructed to use the penile traction device for 4–6 hours a day for 6 months. 44 patients completed the study and at 6 months demonstrated a significant gain of 1.7 ± 0.8, 1.3 ± 0.4, and 1.2 ± 0.4 cm in the flaccid, stretched, and erect penile lengths, respectively. However, penile circumference was measured after 3 months of use, and girth gained was again found to be negligible (9.6 ± 1.1 cm and 9.8 ± 1.1 cm, before and after treatment). International Index of Erectile Function scores and reported device satisfaction favored use of the device, and only 4 patients discontinued use because of mild and reversible adverse outcomes. As the authors discussed, validated measures of patient satisfaction and assessments of participant compliance would be beneficial in investigations of penile traction devices. Although the penile extender offers a favorable safety profile and non-invasive method to achieve durable penile length gain in the physiologically normal penis, the same is not true for girth augmentation and thus should not be recommended in the man exclusively concerned with increasing penile girth.

INJECTION THERAPY

Within the arena of penile girth enhancement, perhaps the foremost area of historical and contemporary research is on penile subcutaneous injection therapy. Descriptive studies detail penile injectables administered by both lay people and medical professionals, from banal materials such as petroleum jelly (Vaseline) or mineral oil to significantly more hazardous materials such as

industrial silicone or metallic mercury.[41–44] Studies on the most commonly used penile injection types are reviewed here (Table 1).

Fat

Autologous fat injection has been described for use in cosmetic and augmentative procedures for decades. Principles of surgery include liposuction fat harvest (typically from abdomen or thigh), fat preparation, followed by subcutaneous injection. Panfilov[11] reported on 88 patients receiving augmentative phalloplasty including autologous fat injection. 40–68 mL of pure fat were injected through small preputial incisions, with a resulting circumference gain of 2.65 cm (range 1.4–4.0 cm), and a durable gain at 1 year of 60–80% of original postoperative gain. Complications were reported in 2.3% of patients, with only 1 patient requiring additional corrective procedures. Similar results were reported by Kang et al,[12] who noted a 2.3-cm mean gain in penile circumference at short-term follow-up (6 months), with only 1 patient developing nodularity.

The sustained gain in penile girth in these studies is surprising given the well-established low survivability of aspirated adipocytes, even when implanted into highly vascularized tissue beds.[45–48] Beyond resorption or degradation of lipocytes, fat-cell rejection and induction of fat necrosis can cause cosmetic complications and functional deficits and can require corrective surgery.[49,50] Wessells et al[51] reported cosmetic complications of autologous fat transfer in 12 patients within 1 year of their penile augmentation procedures, including irregular residual fat nodules, skin deformity, and scarring, as well as scrotalization of penile shaft skin (resulting from concurrent suspensory ligament release and suprapubic V-Y plasty). Sensory disturbances were noted in 2 patients with diminished biothesiometric vibratory sensation in one and pain prohibitive of sexual activity in another.

These serious complications are, however, overshadowed by the tragic death of a 30-year-old man because of fat embolism immediately after penile autologous fat injection.[52] This patient underwent suspensory ligament release and subfascial penile injection of 60 mL of autologous fat, after which he suffered immediate and complete cardiopulmonary collapse. Autopsy with microscopic examination revealed multiple fat emboli in the pulmonary vasculature of all lung lobes. Penile autologous fat injection should thus be regarded as experimental, and potential consequences, both mild, and severe, should be discussed with patients.

Silicone

Use of liquid injectable silicone (LIS) for cosmetic augmentation began in the 1940s in Japan, Germany, and Switzerland, and was popularized in the United States in the 1960s.[53] Early injections of large-volume (liters) LIS were met with disastrous results, most notably silicone migration, prompting its suspension by the FDA in 1976 and its criminalization in Nevada in 1975.[54] The first report of penile injection of LIS occurred in 1973 and involved suprapubic injection of silicone, ultimately requiring resection due to tenderness and inflammation.[55] Host responses to silicone injection can vary but are known to result in the infiltration of multinucleate giant cells, fibroblastic deposition of collagen around pseudocystic vacuoles, and potential obliteration of surrounding microvasculature.[53,56,57] Radiographic evidence of inflammation, abscess formation, silicone migration, and other complications have been reported.[58,59]

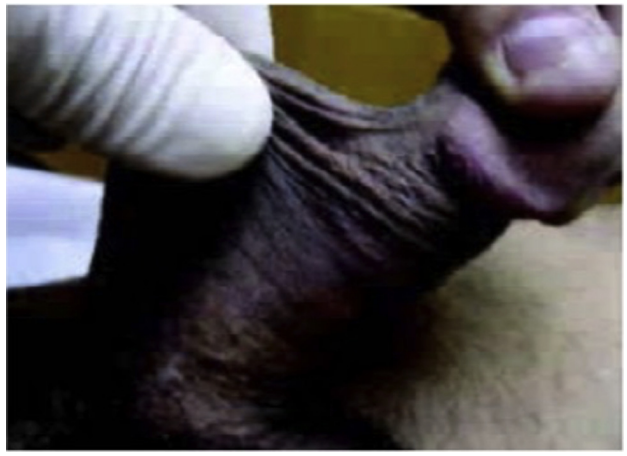

Figure 1. Penile skin tenting to accomplish microdroplet injection technique for liquid injectable silicone as described by Yacobi et al.[13] Figure 1 is available in color online at www.smr.jsexmed.org.

Reports of symptomatic reactions to penile LIS injection include severe edema, penile distortion caused by silicone granulomas, and sexual dysfunction, with adverse events occurring up to 30 years after injection.[60–66] Some patients with these cosmetic and functional complications have required resection and reconstruction, and others have declined intervention.[60,61] In fact, there is a corresponding body of literature focused on reconstructive principles and techniques for treatment of siliconomas.[41,63,65] Regrettably, LIS injection for aesthetic purposes has also resulted in catastrophic consequences including silicone embolism, silicone pneumonitis, and multi-organ failure.[67,68]

The microdroplet technique, which involves application of tiny droplets of silicone (0.01–0.07 mL), was developed to mitigate potential morbidity associated with large-volume LIS injection.[55] Yacobi et al[13] described their experience using this technique in an incremental fashion to enhance penile girth. They reported on 324 patients who underwent a series of injection treatments (mean 5 treatments, range 3–6) with ultrapurified LIS (Siluron 1000; Fluron GmbH, Germany). During each treatment, 5-mL LIS was injected into the areolar tissue between tented penile skin and Buck's fascia, with ≥30-day intervals between treatment sessions (Figure 1). Only 30 patients in the study cohort had girth parameters measured before and after treatment, and in this small fraction there was a mean increase in circumference of 2.6 cm (27%) at mean follow-up 20 months (range 1–36). 21 patients reported improved erections and resolution of premature ejaculation, and no complications were reported. The authors attributed their success and

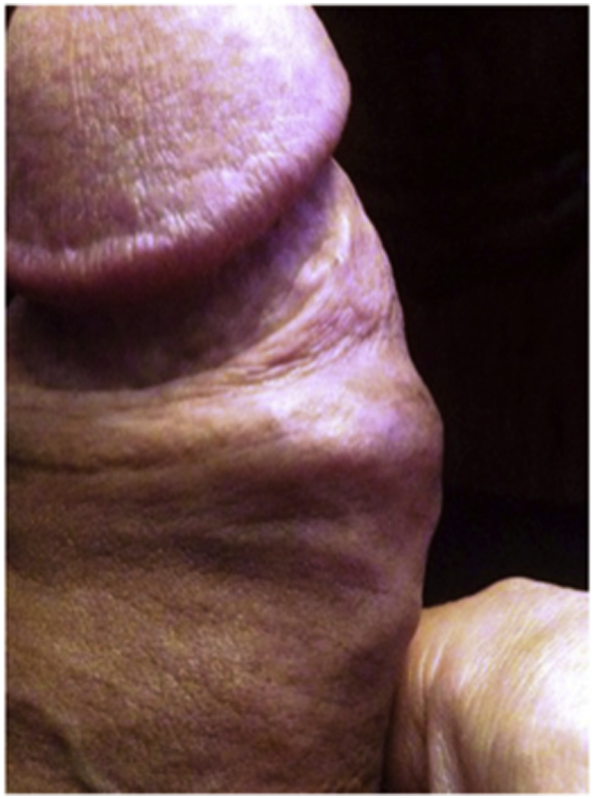

Figure 2. Penile shaft nodularity and irregularity seen in 52% of men after PMMA injection.[15] Figure 2 is available in color online at www.smr.jsexmed.org.

lack of adverse outcomes to use of the microdroplet injection technique in a gradual manner, as well as to the purity of the product used for LIS. Unfortunately, this study is limited primarily by absence of objective data on 90% of the larger cohort, as well as lack of long-term follow-up, particularly given the prolonged interval at which silicone complications can occur.[64]

Although LIS injection has been used with success for other specific indications, the safety and efficacy of LIS injections for penile girth enhancement have yet to be defined, and use outside of a clinical protocol should be discouraged. Yacobi et al[13] offer a glimpse of positivity using the microdroplet technique; however, more rigorous reporting with long-term follow-up is essential.

Soft Tissue Fillers

Cosmetic soft tissue filler use has increased 312% since 2000 and accounts for almost 2.7 million procedures annually.[69] Agents including hyaluronic acid, calcium hydroxylapatite, collagen, polymethyl-methacrylate microspheres (PMMA) and several others, are used for countless types of minimally invasive cosmetologic procedures and have been examined for use in penile augmentation.

Hyaluronic acid (HA) is a long-lasting, resorbable dermal filler that has a well-established safety profile, as well as FDA approval in many forms.[70] In 1 report of 41 men receiving HA injection for penile girth enhancement, patients underwent a single treatment with a mean volume of 20.56 mL.[14] Mid-shaft penile circumference was significantly increased from 7.48 ± 0.35 cm to 11.4 ± 0.34 cm at 1 month and 11.26 ± 0.33 at 18 months. All patients estimated good retention of girth gained at 18 months; however, patient satisfaction declined markedly from month 1 to month 18. The authors attribute the diminished satisfaction to a disturbance of erectile rigidity, because the corpora cavernosa were covered with softer HA after the procedure. Additionally, most patients experienced decreased tactile sensation of the shaft. Despite this substantial negative effect on sexual functionality and perhaps enjoyment, there were no deformities, inflammation, or adverse events reported. Unfortunately, in other series, HA injection has been associated with major complications including vascular occlusion caused by arterial embolization after facial injection, as well as severe hypersensitivity after penile injection.[71,72] Arterial embolization has not been reported after penile injection of HA.

PMMA is a non-absorbable soft tissue filler that has been preferentially used in some populations because of its permanence. Microspheres of PMMA are encapsulated into granulation tissue, after which collagen and vascular tissue can embed the microspheres.[15] Casavantes et al[15] reported on their 8-year experience with serial PMMA injections for penile girth enhancement, having performed 1,500 injection procedures on 729 men, including a large number of patients who had previously undergone other girth enhancement procedures. The prescribed treatment regimen resulted in an average increase in penile girth of 2.4 cm, which was sustained in flaccid, stretched, and erect states (as measured by patients). Interestingly, patients also experienced an increase in flaccid length of 0.7 cm, which the authors attribute to the stiffness of the PMMA implant, begging the question about the ability of this filler material to create a natural, supple feeling penile shaft in the flaccid state. Indeed, a majority of patients (52%) reported nodularity, ridges, irregularity, indentations, or voids in tissue filler (Figure 2). Satisfaction surveys were returned by 203 (28%) patients, of whom 168 (83%) were satisfied, and 17% were either not satisfied or dissatisfied. The authors briefly alluded to the potential difficulty and radical surgery required to remove a PMMA implant, which was the unfortunate reality for 1 patient presenting with severe penile deformity, erectile dysfunction, pain during intercourse and diffuse penile fibrosis after one PMMA injection, ultimately necessitating complex reconstruction (Figure 3).[73]

Overall, there is a dearth of prospective studies with long-term follow-up, and reproducible results in this arena, and thus we lack evidence-based clinical guidelines on dermal fillers for penile girth enhancement. Use of these products in men with PDD should be considered off-label and approached with caution.

GRAFT AND FLAP PROCEDURES

Dermal fat grafts are free onlay grafts consisting of de-epithelialized dermis and subcutaneous fat, the former of which is

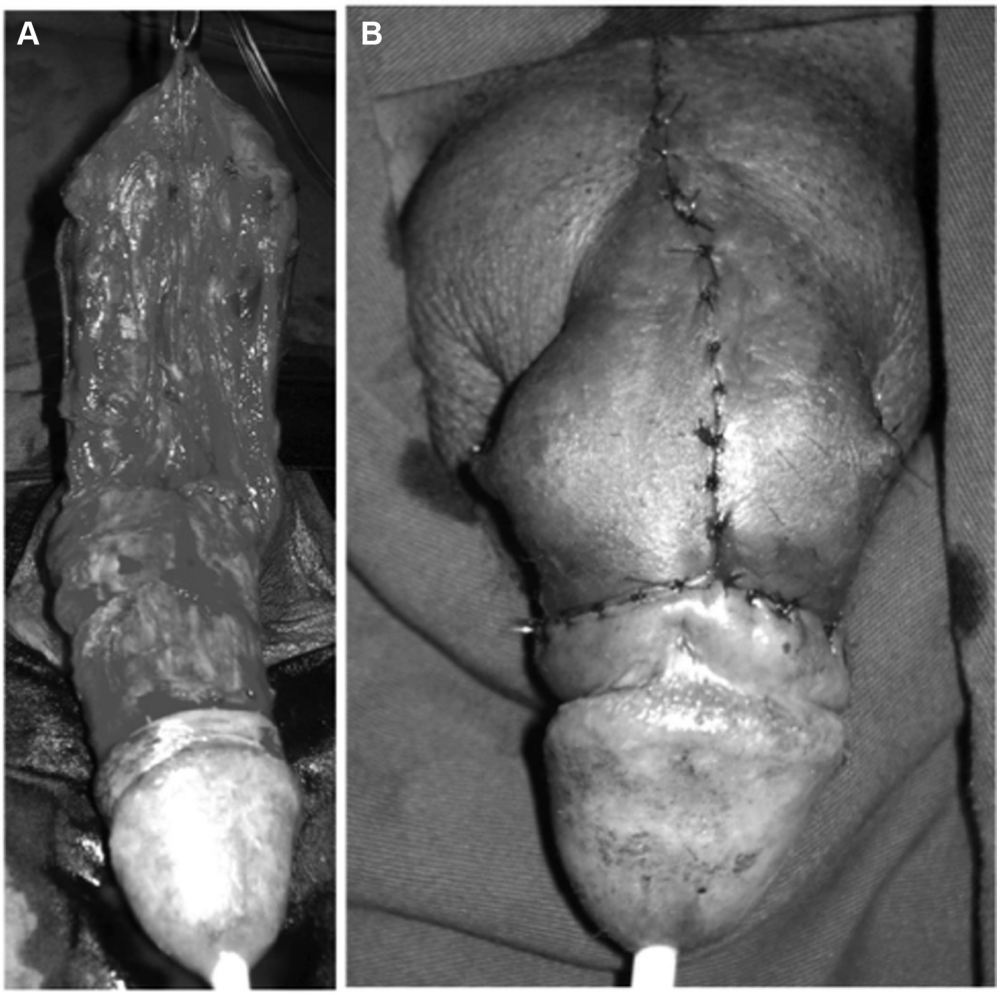

Figure 3. Resection of PMMA implant due to penile fibrosis and sexual dysfunction. A, Resection of mass and skin. B, Postoperative appearance.

important in increasing bulk and blood vessels to aide in graft vascularization.[74] Graft harvest is required, with 1 study using groin harvest sites measuring approximately 10 × 5 cm.[16] Spyropoulos et al[16] reported on a variety of penile augmentation techniques, including penile shaft enhancement with dermal fat graft in 4 patients. Mean girth gained with this approach was 2.3 cm at the base and 2.6 cm at the corona. Unfortunately, the listed complications were not linked with their associated augmentative procedures but did include preputial edema or paraphimosis in 27% (3 of 11), pain on erection in 27% (3 of 11), and 1 patient with dermal-fat graft sclerosis resulting in temporary curvature and pain with erection (9%). It will be important to see whether these high rates of complication hold true in larger cohorts, along with other reported complications such as sustained penile deformity due to graft fibrosis, skin loss, penile hypoesthesia, as well as donor-site related issues.[16]

Whether the use of a fasciocutaneous arterial island flap supplied by a vascular pedicle can mitigate some of the complications of free dermal grafts is unclear because there is only 1 case report to date.[75] The added level of surgical complexity, operative time (4.5 hours), and microvascular expertise immediately makes this procedure poorly generalizable and, most importantly, unjustifiable to offer to young men with physiologically normal penises.

Alei et al[17] obviated the need for a graft harvest site by using a porcine dermal acellular matrix graft (InteXen; American Medical Systems, Minnetonka, MN, USA), which is indicated for pelvic organ prolapse surgery. In their report, 69 patients underwent placement of 1 layer of xenograft through a small infrapubic incision (Figure 4). Girth parameters significantly increased in both the flaccid and erect states from before surgery (mean 8.1 cm and 10.8 cm, respectively) to 1 year after surgery (mean 11.3 and 13.2 cm, respectively). Additionally, the Augmentation Phalloplasty Patient Selection and Satisfaction Inventory, a non-validated questionnaire, revealed significant improvements in sexual self-esteem and satisfaction with surgical results in 68 of 69 patients.[76]

The high rate of satisfaction in this study seems remarkable given the significant number of patients who experienced graft fibrosis (9 of 69, 13%), which resulted in penile retraction by a

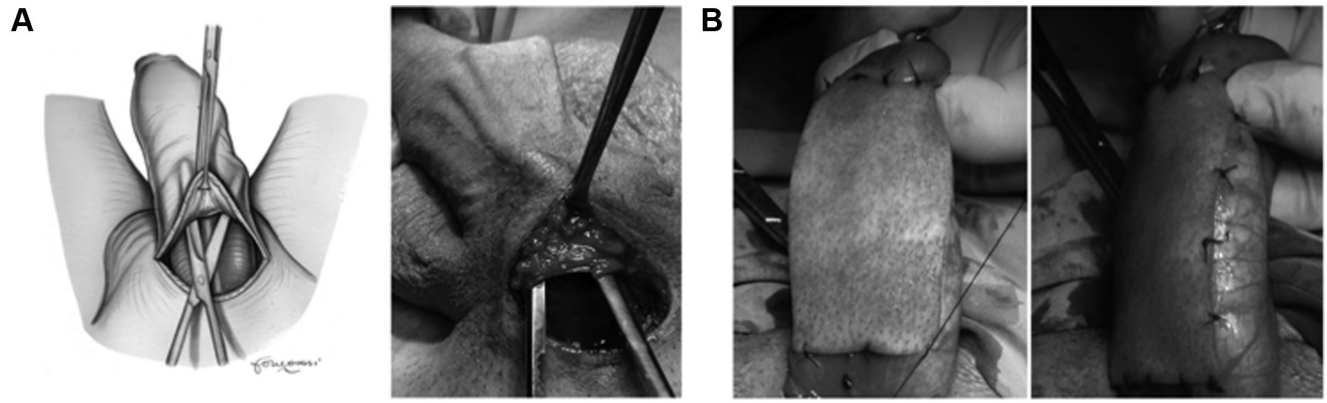

Figure 4. Placement of porcine dermal acellular graft. A, Dissection between Colles' and Buck's fascia through penopubic incision. B, Suturing graft to Buck's fascia.[17]

mean of 0.52 cm. In a population of patients going to extreme lengths to augment their penile dimensions, it seems questionable to offer a procedure that results in penile shortening in almost 1 in 10 men.

In fact, in a recent pilot study of a related acellular collagen matrix graft (Pelvicol; CR Bard, Inc., Covington, GA, USA), Tealab et al[18] found a significantly worse satisfaction rate, with only 2 of 18 implanted patients reporting high postoperative satisfaction. Several patients experienced severe penile edema and ulceration or infection, with 4 of 18 (22%) necessitating removal of the graft (Figure 5). Diminished penile sensation was also reported by 4 of 18 (22%) patients. This study highlights the need for objective reporting of postoperative penile shaft sensitivity and complication data using a validated instrument collected by an independent practitioner to evaluate post-augmentation satisfaction.

SUBCUTANEOUS PENILE IMPLANTS

The growing market for aesthetic male genital enhancement has led to the development of not only novel procedures, but also new devices and implants. 1 such device is the subcutaneous silicone implant (Penuma; International Medical Devices, Los Angeles, CA, USA), which received patent approval in 1995.[77] The Penuma device, which wraps around the dorsal three-quarters of the penile shaft, is inserted subdermally through a suprapubic incision and affixed to the glans with polyester mesh, leaving the proximal end free-floating under the patient's pubic bone (Figure 6).[78] The device inventor authored a report on 3 patients who underwent insertion of the subcutaneous silicone implant and were followed up for a mean of 6.7 months.[78] There were no complications during this follow-up period, and, when answering a brief satisfaction questionnaire, no patients were dissatisfied with their results. Mean girth increase in this case report was 3.0 ± 1.0 cm. Sexual function, penile sensation, and partner satisfaction were not assessed.

The same group then retrospectively reviewed their experience with 526 patients who underwent silicone block implantation from 2009 to 2014, reporting on satisfaction and adverse events in 400 patients (76%) who consented to participate in a post-operative questionnaire.[79] 12 patients (3%) required device removal for implant breakage with implant perforation and infection (1%), implant infection (1%), suture detachment (0.5%), implant breakage (0.25%), and hematoma (0.25%). Unfortunately, long-term sequelae of such adverse events and implant removal, such as penile shortening, fibrosis, and sexual dysfunction were not discussed. Furthermore, it seems that not all patients experiencing complications of such procedures are managed by the surgeons implanting them. Hebert et al[19] reported on 8 patients presenting to their neighboring institution with

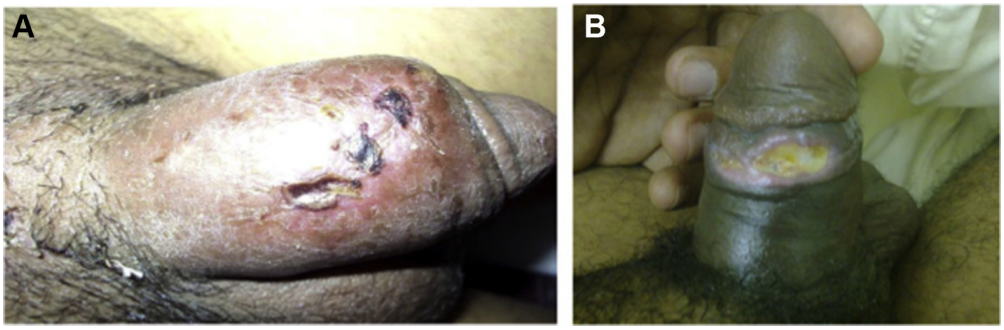

Figure 5. Complications of acellular collagen matrix graft. A, Infection requiring graft removal. B, Ulceration managed conservatively.[18] Figure 5 is available in color online at www.smr.jsexmed.org.

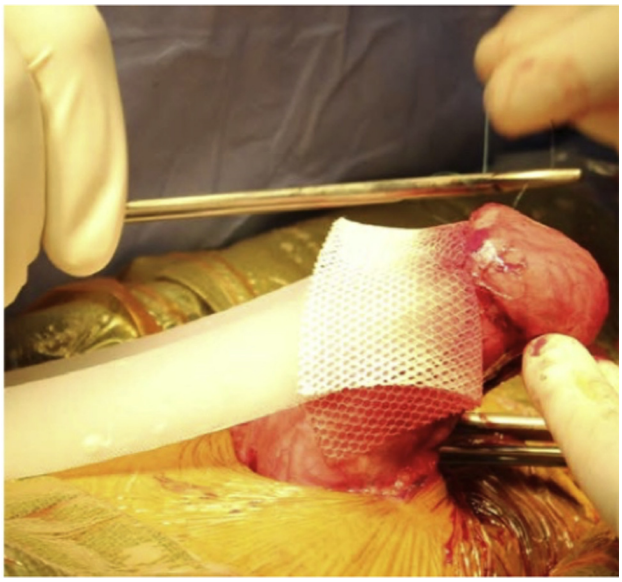

Figure 6. Suturing of silicone sleeve implant to glans using polyester mesh. Proximal end remains unsutured.[78] Figure 6 is available in color online at www.smr.jsexmed.org.

complications of penile augmentation surgery, including 5 patients who had undergone subcutaneous silicone implant placement and subsequent removal. At presentation, observed adverse changes included severe edema, subcutaneous masses, penile curvature, or other sexually disabling deformity, infection, non-healing wounds, and scarring (Figure 7). 7 patients (88%) required operative management, with 25% requiring multiple corrective surgeries and 25% requiring split-thickness skin grafting. Even after undergoing rescue surgeries, erectile function remained diminished with a mean Sexual Health Inventory for Men score of 18.

Device development and ingenuity are at the heart of technological advancement in surgery and can ultimately provide patients with greater longevity and quality of life. Regrettably, use of devices without clearly defined safety profiles may be to the detriment of vulnerable patients who are offered a panacea to their distress, anguish, and low self-esteem. Rigorous investigation with accurate reporting of complications should be mandated before more men take on the physical, mental, and significant financial burden associated with subcutaneous silicone penile implants.

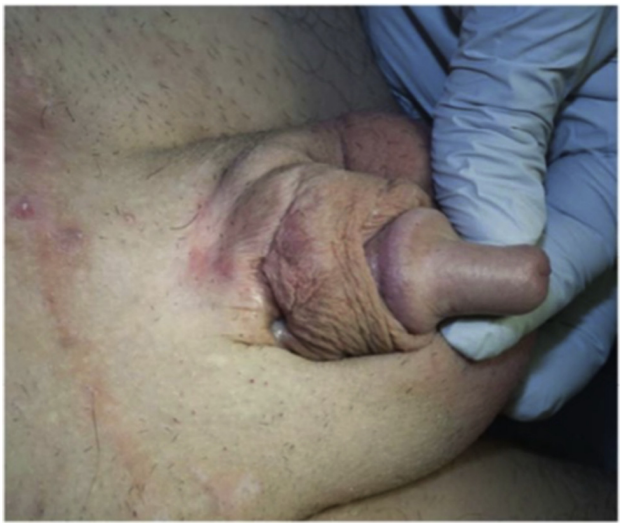

Figure 7. Patient presenting with open wound and severe deformity after failed dermal matrix graft and 2 failed subcutaneous silicone implants.[19] Figure 7 is available in color online at www.smr.jsexmed.org.

CORPOROPLASTIC PHALLOPLASTY

Corporoplastic augmentation surgery uses bilateral corporal venous grafts to expand corporal girth and was described by Austoni et al.[80] During this procedure, bilateral longitudinal corporal incisions are made into the lateral aspect of the tunica albuginea from glans to pubis, where harvested saphenous vein grafts are then placed for augmentation (Figure 8). Circumcision is recommended in all patients to prevent severe preputial edema.

The authors reported on their experience with 39 patients, approximately half of whom had PDD and normal penile diameter ($\geq$2.5 cm).[80] At 9 months' follow-up, erect penile diameter had increased an average of 1.36 cm (4.2 cm circumferential gain). In the subset of men with normal preoperative penile diameter (mean 3.56 $\pm$ 0.22 cm), mean penile diameter gained was 1.26 cm (2.9 cm circumferential gain). Change in penile girth in the flaccid state was clinically irrelevant and subjectively imperceptible. No major adverse events occurred, and the temporary penile curvature that occurred in 40% of patients resolved at 3 months. Nocturnal penile tumescence was unchanged from before to after surgery, demonstrating preservation of erectile rigidity.

This technique uses the well-established principle of corrective incision and grafting for penile deformity such as PD and applies it to individuals with PDD. Patient selection of men with good erectile function before surgery is critical, as is establishing proper expectations. This procedure does not offer girth expansion in the flaccid state and thus should not be offered to men who are concerned with inadequate flaccid appearance, but rather to men who are motivated to augment erectile girth. This is a radical and invasive technique that has strict applications in the PDD population and should be regarded as experimental until further well-designed studies are reported.

A variety of adjunctive penile girth and length preservation or enhancement procedures have also been described for implementation at the time of inflatable penile prosthesis insertion. Although beyond the scope of this review, Tran et al[20] concisely described these techniques, which range from HA injection for glans augmentation to more highly complex reconstructive procedures such as the sliding technique, modified sliding technique, and augmentation corporoplasty. One major caveat to performing such advanced augmentative procedures with concomitant inflatable penile prosthesis insertion is the risk of glans necrosis, particularly in the man with severe systemic vascular disease.[81]

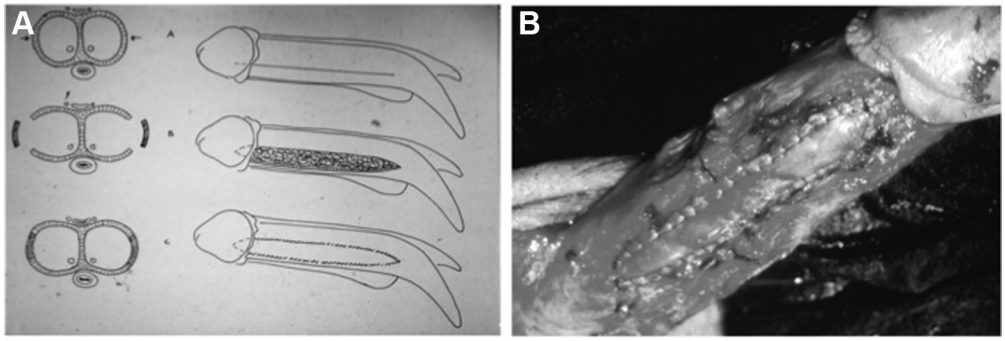

Figure 8. Corporal augmentation phalloplasty. A, Schematic showing insertion of saphenous vein graft into bilateral longitudinal incisions of tunica albuginea. B, Intraoperative photo of albugineal vein graft.[80]

CONCLUSIONS

In an era of growing emphasis on physical appearance, PDD is ever more important to recognize and treat appropriately. The psychological distress, diminished quality of life, and impairment in sexual function associated with PDD are important aspects of any comprehensive assessment. Addressing these issues should be central to any therapy protocol, because it has been shown that a vast majority (96.4%) of patients receiving cosmetic procedures for BDD reported worsening or no change in symptoms of BDD.[82] Barring any contraindications, trials of fluoxetine and PDE5 inhibitors may be initiated in the setting of PDD before more-invasive, procedural treatments. Psychological evaluation and counseling should be implemented for every patient considered for penile augmentation procedures.

It is paramount to counsel patients that although a variety of penile girth augmentation techniques have been studied, clinical guidelines are lacking, and there are still no accepted standardized methods to determine the physical, clinical, and psychological benefits of these interventions. Furthermore, complications of penile girth enhancement are likely widely underreported. Until more rigorous multi-institutional investigation with accurate reporting of complications is achieved, penile girth augmentation procedures should be considered experimental. It should be with caution that we approach invasive procedures intended to treat psychiatric disorders. Further investigations of penile girth enhancement techniques should clearly report both physiological and psychosocial outcomes measured with validated instruments.

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